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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/658,862	STOCKMAN CAMPBELL ET AL.	
	Examin r	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *57-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/803,165.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant is advised that the examiner of this application is scheduled to move to the new Patent and Trademark Office complex on January 12, 2004. New telephone numbers, effective the move-date, for the Examiner and SPE of AU 1632 are found at the end of this office action.

Applicant's arguments filed August 22, 2003 have been fully considered but they are not persuasive. The amendment has been entered. Newly issued rejections over claims 69, 70 and 72-851 have caused this office action to be non-final. Claims 57-86 are pending.

Applicant's amendment to claims 57-68 and 71 that the pre-existing mammal is an "non-embryonic" mammal overcomes the statutory type (35 U.S.C. 101) double patenting rejection of claims 92-127 and 130 of copending Application No. 09/225,233 made in the office action mailed May 9, 2003.

Applicant's amendment to claims 57, 61, 69 and 70, deleting the phrase "same set of chromosomes," has overcome their rejection under 35 U.S.C. 112, first paragraph as lacking written description made in the office action mailed May 9, 2003.

Applicant's arguments to claims 69 and 70 have over come the their rejection under 35 U.S.C. 112, first paragraph as lacking written description made in the office action mailed May 9, 2003. While the examiner concedes that specification discloses the pre-existing mammal and a clone of the pre-existing mammal, and a clone produced from a cell or a cell culture prepared from the pre-existing mammal, applicant is put on notice that the examiner does not find support for these products to be "a combination" or " composition" as examples. The specification only discloses these products separately and not in any "unit" form. An amendment to claims 69, 70 and/or 72-86 to indicate that the products are some sort of unit may result in a rejection for lacking adequate written description at the time of filing.

Applicant's amendment and arguments have overcome the rejection of claims 57, 61, 65, 67 and 69-71 under 35 U.S.C. 112, second paragraph as set forth in the office action mailed May 9, 2003. In particular, applicant argues (response filed August 22, 2003) that in the claims, "is capable of developing to term" is a functional limitation that requires the embryo have the capacity for full-term development. In claims 65 and 67, the amendment clarifies the transgenic nature of the cloned mammal. In claims 69 and 70, applicant's amendment to the claims clarifies the nature of the clone.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57-68 and 71 are provisionally rejected (new) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 92-127 and 130 of copending Application No. 09/225,233. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not

patentably distinct from each other because present claims 57-68 and 71 are a species of cloned nonhuman mammal within the scope of cloned nonhuman mammal of claims 92-127 and 30 of '233. The scope of pre-existing, non-embryonic mammal of present claims 57-68 and 71 includes "adult" as in claims 92-127 and 130 of '233, given the specification's definition of the term. Therefore, at the time of the present invention, it would have been obvious to the ordinary artisan that present claims 57-68 and 71 are contained with the scope of claims 92-127 and 130 of '233.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 69, 70 and 72-86 are provisionally rejected (new) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 128, 129 and 131-145 of copending Application No. 09/225,233. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping and obvious scope given the definitions of the terms in the relevant specifications. The differentiated donor cells and cell preparation of present claims 69, 70 and 72 is a species to the genus somatic donor cell and cell culture of claims 128, 129 and 131-145 of '233. Further, stating that the clone is nonhuman, non-embryonic mammal in present claims 69, 70 and 72-86 renders these claims a genus to an adult mammal in of claims 128, 129 and 131-145 of '233. Therefore, at the time of the present invention, it would have been obvious to the

ordinary artisan that present claims 69, 70 and 72-86 and claims 128, 129 and 131-145 of '233 are of obvious and overlapping scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 57-68 and 71 are rejected (new) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U.S. Patent No. 6,525,243 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the products of claims 57-68 and 71 can be made by the methods of claims 1-16 in '243.

Claims 57-68 and 71 are drawn to nonhuman mammals produced by a particular method of cloning by somatic cell nuclear transfer. Claims 1-16 of '243 are to a method of cloning that is separate from the method claimed presently to produce the nonhuman mammals of the present claims. However, as the method of claims 1-16 of '243 would produce the same mammals as those of present claims 57-68 and 71, the claims of '243 would make obvious the nonhuman mammals of the present claims. Thus, at the time of the present invention, it would have been obvious to the ordinary artisan that that present claims 57-68 and 71 would be obvious over claims 1-16 of '243.

Claims 57-68 and 71 are rejected (new) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-21 of U.S. Patent No. 6,147,276. An obviousness-type double patenting rejection is appropriate

where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed cloned nonhuman embryos and cloned nonhuman mammals can be made by the process claimed in '276.

Claims 57-68 and 71 are drawn to nonhuman mammals produced by a particular method of cloning by somatic cell nuclear transfer. Claims 1-10 and 13-21 of '276 are to a method of cloning that is separate from the method claimed presently to produce the nonhuman mammals of the present claims. However, as the method of claims 1-10 and 13-21 of '276 would produce the same mammals as those of present claims 57-68 and 71, the claims of '276 would make obvious the nonhuman mammals of the present claims. Thus, at the time of the present invention, it would have been obvious to the ordinary artisan that that present claims 57-68 and 71 would be obvious over claims 1-10 and 13-21 of '276.

Claims 57-68 and 71 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11-18 of U.S. Patent No. 6,252,133 B1 for reasons set forth in the office action mailed May 9, 2003.

Applicant agreed to file a terminal disclaimer to U.S. Patent No. 6,252,133 B1 once allowable subject matter is identified.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 57-86 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 92-145, as written, do not sufficiently distinguish over nonhuman mammals, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Thus, the claims lack evidence of the hand-of-man. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105.

In particular, the claims are drawn to cloned nonhuman mammals produced by somatic cell nuclear transfer. However, the cloned mammals are not described, nor claimed, as having a new phenotype that would distinguish them from any previously existing or presently existing mammal of the same species. For example, a sheep produced by cloning would not have any features that patentably distinguishing the cloned sheep from the somatic cell donor sheep. The cloned sheep still functions as the donor sheep, and has no features that render new or an improvement over the prior existing sheep

It is noted that applicant, in response to the art rejections made in the office action mailed May 5, 2003, have stated that the cloned sheep is not strictly identical to the donor in that the clone has genomic DNA nucleotide variations. However, the genome of all mammals of the same species is probably not 100% identical. It is accepted that there is nucleotide variation among species but that such variations are silent and do not affect the mammal's physiology, biochemistry or use. Therefore, a silent alteration to the genomic sequence of a mammal does not provide for a new mammal or a new or useful improvement of the mammal as required for patentability. Further, the claims clearly state that the mammal is the clone of a prior existing mammal, indicating that the clone is a replica.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 86 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 86 is to a pair of live-born, non-human mammals comprising a parental nonhuman mammal and its offspring clone. However, the specification never contemplates a pair of non-human mammals. The specification discloses nonhuman mammals as nuclear donors and nonhuman mammals as the clone of the donor, and contemplates them singularly. However, the specification never contemplates them as a pair.

To meet written description, the claimed invention must have been described in the specification as filed. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Thus, while applicant might have written description for an adult, parental nonhuman mammal and it live offspring clone; there is no such description of the adult and offspring as a pair.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65, 69, 70 and 72-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 69, 70 and 72-86 are to two products. However, the products are not indicated as being part of a composition, combination or some other term indicating the relationship of the products to each other. Thus, it is not clear how the products exist in relation to each other such that infringement would be apparent. For example, the claims do not indicate if the two products have to exist at the same time, exist in the same geographical location, or exist in the same physical location. Therefore, the metes and bounds of claims 69, 70 and 72-86 are not clear to the reader.

Claim 65 lack antecedent bases for "wherein the embryo clone is produced by a process comprising" as the claims is no longer to a cloned nonhuman mammalian embryo (see original claim 65, line 3).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57-64 and 71 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reasons set forth in the office action mailed May 9, 2003, by or in the alternative, are rejected over U.S. Patent 5,057,420 issued October 15, 1991 (Massey).

Massey teaches bovine embryos isolated from cows that have been artificially inseminated (col. 3, lines 18-31). Bovine embryos and bovines encompassed by the present claims and made by a particular process of the claims do not have a property that distinguishes them from those bovine embryos and bovines taught by Massey. Producing the claimed embryos and bovines by cloning from a differentiated cell taken from a non-embryonic mammal does not provide a distinguishing feature to the resultant embryo, as the source of the embryo's chromosomes does not affect the embryo.

In the alternative the bovine embryos and bovines taught by Massey render the claimed bovine embryos and bovines obvious because there is no disclosed or discernable patentable distinction between Massey's bovine embryos and bovines and those claimed. However, applicant has argued that there would be genomic DNA nucleotide differences between the bovine embryos and bovines of Massey and those claimed. There is no evidence that any of these purported differences materially alter the bovine embryos or bovines to provide patentable distinction over the bovine embryos and bovines of Massey. Thus at the time of the present invention, the ordinary artisan would have found the claimed bovine embryos and bovines obvious over the bovine embryos and bovines disclosed by Massey.

Claims 61-64 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reason set forth in the office action mailed May 9, 2003, by or, in the alternative, are rejected over The Science of Providing Milk for Man, Campbell and Marshall, McGraw Hill Book Co., New York, 1975, pages 48, 49, and 51-56

At pages 48,49 and 51-56, Campbell and Marshall teach several different bovines that existed prior to applicant's invention. A bovine produced by the claimed methods would not be patentably distinct from any one of the bovines of Campbell and Marshall as the method of producing does not provide a patentably distinguishing feature to the claimed mammal. That the claimed mammals have the same set of chromosomes as a nonhuman, non-embryonic mammal does not provide a distinguishing feature to the resultant mammal, as the source of the mammal's chromosomes does not affect the mammal.

In the alternative the bovines taught by Campbell and Marshall render the claimed bovines obvious because there is no disclosed or discernable patentable distinction between Campbell and Marshall's bovines and those claimed. However, applicant has argued that there would be genomic DNA nucleotide differences between the bovines of Campbell and Marshall and those claimed. There is no evidence that any of these purported differences materially alter the bovines to provide patentable distinction over the bovines of Campbell and Marshall. Thus at the time of the present invention, the ordinary artisan would have found the claimed bovine obvious over the bovines disclosed by Campbell and Marshall.

Claims 57-64 and 71 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reasons presented in the office action mailed May 9, 2003, by or, in the alternative, are rejected over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147

Sims teaches the production of bovines and bovine embryos by nuclear transfer, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). The source of the donor nucleus, be it bovine inner cell mass cell or a non-embryonic differentiated cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the bovine embryo or bovine such that the

bovine embryo or bovine encompassed by applicant's claims is patentable distinct from those of Sims et al.

In the alternative the bovine embryos and bovines taught by Sims render the claimed bovine embryos and bovines obvious because there is no disclosed or discernable patentable distinction between Sims's bovine embryos and bovines and those claimed. However, applicant has argued that there would be genomic DNA nucleotide differences between the bovine embryos and bovines of Sims and those claimed. There is no evidence that any of these purported differences materially alter the bovine embryos or bovines to provide patentable distinction over the bovine embryos and bovines of Sims. Thus at the time of the present invention, the ordinary artisan would have found the claimed bovine embryos and bovines obvious over the bovine embryos and bovines disclosed by Sims.

Claims 65-68 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reasons presented in the office mailed May 9, 2003, by or, in the alternative, are rejected over WO 95/17500 published 29 June 1995 (Stice).

Stice teaches transgenic nonhuman mammalian embryos and transgenic nonhuman mammals produced by nuclear transfer where the nuclear donor is an embryonic cell comprising a genetic modification (page 33, lines 14-24). The source of the donor nucleus, be it a genetically modified nonhuman embryonic cell as Stice teaches or a genetically modified non-embryonic, nonhuman mammalian differentiated cell as claimed, does not provide a patentable distinction on the resulting genetically modified nonhuman embryo or genetically modified nonhuman mammal. The source of the donor nucleus does not alter the embryo or mammal such that the embryo or mammal encompassed by applicant's claims is patentable distinct from those of Stice et al. Further, Stice teaches that the cells are cultured *in vitro* and are abstracted *ex vivo* (page 6144, 1, 8-15).

In the alternative the transgenic nonhuman mammals and mammalian embryos taught by Stice render the claimed transgenic nonhuman mammals and mammalian embryos obvious because there is no disclosed or discernable patentable distinction between Slice's transgenic nonhuman mammals and mammalian embryos and those claimed. However, applicant has argued that there would be genomic DNA nucleotide differences between the transgenic nonhuman mammals and mammalian embryos of Stice and those claimed. There is no evidence that any of these purported differences materially alter the transgenic nonhuman mammals and mammalian embryos to provide patentable distinction over the transgenic nonhuman mammals and mammalian embryos of Stice. Thus at the time of the present invention, the ordinary artisan would have found the claimed transgenic nonhuman mammals and mammalian embryos obvious over the transgenic nonhuman mammals and mammalian embryos disclosed by Stice.

Applicant argues that their claimed mammals and embryos are novel, and they can't be anticipated by mammals and embryos known in the art because the claimed mammals and embryos are clones of pre-existing, nonembryonic mammals. Applicant argues that in a similar fashion that the claimed transgenic mammals are cloned offspring of pre-existing nonembryonic mammals that additionally contain a genetic modification.

Applicant argues that their claimed mammals are not strictly identical to the mammals of the prior art, as no two mammals are exactly the same. Applicant argues that among other factors, differences in oocyte contributions and uterine environment will lead to phenotypic differences between any two mammals. Applicant argues that their mammals cannot be anticipated because they did not previously exist.

Applicant argues that the mammals of the prior art exist during a specified period of time during which they are alive. Applicant argues that each of the mammals of the prior art was born on a specific day, and that none of applicant's claimed clones were born on the

same day as any of the mammals of the prior art. Applicant argues that because of the separate birthdays, the claimed mammals are "time-delayed" copies, and that this is an inherent phenotypic feature of applicant's clones. Applicant argues that their discovery has lead to the avoidance of extinguishing a mammal's unique genetic contribution at death. Applicant argues that a clone will always be younger that the pre-existing, nonembryonic mammal from which it was generated. Applicant argues that because the clone exists at different time period than the mammals of the prior art, a distinction is provided between applicant's claimed mammals and the mammals in the prior art. Applicant argues that the age difference between a cloned mammal and a prior existing mammal provides patentable distinction. Applicant argues that the genomic DNA of a cloned mammal, the time-delay generated by cloning and environmental influences, assure that applicant's cloned mammals are distinct from those mammals that previously existed.

Applicant's arguments are not persuasive.

The examiner agrees that the complete genomic sequence between any two mammals, or mammalian embryos, might have absolute nucleotide sequence differences. However, the specification does not discuss these differences or what new property/phenotype is given the mammal or mammalian embryos based on the genomic DNA differences. Any such differences appear to be silent that is they have no effect on the clone. The clone, therefore, does not have a new property/phenotype that makes it patentably distinct from the prior existing mammal. Likewise, age differences between the prior existing mammal and the cloned mammals of the claims do not affect the overall use of the clone over prior existing mammal. Further, "phenotype" is a term of genetic meaning "the appearance or physical structure of an individual" (Molecular Biology of the Gene, 4th ed., Watson et al. The Benjamin/Cummings Publishing Company, Menlo Park, CA., 1987, pages 9-10, bridg. sent.) Based on this definition, "age" or an "age difference" is not a

phenotype as the are not part of the physical structure of an individual. Therefore, a silent alteration to the nucleotide sequence is not seen as providing patentable distinction between a prior existing mammal and a clone of that mammal.

To carry applicant's arguments to their logical conclusion, a female calf born today would be patentable over its mother. There would be some difference in genomic DNA nucleotide sequence between cow and calf, and the mother is obviously older than the calf. However, these differences do not provide the calf or the clone with any new traits over the mother or the prior existing mammal. Also, applicant's argument would permit the patenting of any animal over any other animal of the same species based upon silent differences or age differences between the two. Furthermore, while the prior existing mammal or mammalian embryo might, and perhaps even probably, have genomic DNA nucleotide sequence differences, applicant has not provided any evidence that the finding of differences is always the case. Fundamentally, applicant's allegations of nucleotide sequence, or other differences between the prior existing mammal and mammalian embryos, is unsubstantiated, and is based on a theory and not a fact.

The closest authority that the examiner could find is *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). The MPEP discusses *Ex parte* Gray in stating "The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish

unexpected properties since the materials appeared to be identical or only slightly different". See MPEP 2113.

The Board of Appeals in Gray states that the dispositive issue is whether or not the factor of the claims exhibited any unexpected properties compared with the factor of the prior art. In the present situation, the cloned mammals and cloned mammalian embryos have not been shown to have any unexpected properties over the mammals and mammalian embryos of the prior art.

Rejection of claims 69, 70 and 72-86 (new).

Claims 69, 70 and 72-86 say nothing as to where or when the mammals and cell cultures exist. The claims indicate no relationship between them. That is to say, the claims do not indicate that the cells and the mammals need to be alive in the same time, or be in the same room, facility, continent and so forth. Further, any reference to "clone" is read as a "method of making by somatic cell nuclear transfer." The method of making a so identified product is not given patentable weight. The rejections below have been made in light of these readings of the claims.

Claims 69 and 86 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morris et al (1993) J. Reproduc. Fertil. 97, 255-261.

Morris teaches a heifer that gave birth to twin calves (page 259, col. 1, parag. 1). Thus, the heifer and either of the twin calves anticipate, respectively, the nonhuman, nonembryonic mammal from which a differentiated donor cell has been taken and clone of the mammal (claim 69). Additionally, the heifer and either of the twin calves anticipate a pair of live-born, nonhuman mammals comprising a parental nonhuman mammal and its offspring produced by cloning (claim 86). The term "pair" in claim 86 is given the broadest definition of "two." Morris clearly anticipates the claimed invention.

In the alternative the heifer and twin calves taught by Morris render the claimed nonhuman mammal and its clone (claim 69) and the claimed pair of nonhuman mammals (claim 86) obvious because there is no disclosed or discernable patentable distinction between Morris heifer and calves, and the mammals claimed. There is no evidence there are differences between the mammals of the claims and those of Morris that materially alter the claimed nonhuman mammals to provide patentable distinction over the heifer and calves of Morris. Thus at the time of the present invention, the ordinary artisan would have found the claimed pair of nonhuman mammals obvious over the heifer and calves disclosed by Morris.

Claims 70, 72, 73, 79, and 80 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Salamonsen et al (1991) J. Cell Sci. 100, pp. 381-385 (sheep).

Salamonsen teaches a preparation of sheep primary endometrial stromal fibroblasts where the fibroblasts were isolated from an ewe (page 382, col. 1, parag. 4). In so teaching, Salamonsen inherently teaches a live-born sheep. Thus, the primary fibroblasts and sheep donor of Salamonsen cannot be distinguished from the claims, which encompass a sheep fibroblast primary cell preparation and a sheep cloned from a cell of the preparation. If the primary fibroblast preparation and donor sheep of Salamonsen were compared side-by-side to claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the sheep. Thus, Salamonsen clearly anticipates the claimed invention.

In the alternative the sheep primary endometrial fibroblasts preparation and live-born sheep taught by Salamonsen render obvious the claimed cell preparation and sheep as there is no disclosed or discernable patentable distinction between Salamonsen's cell preparation and sheep those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited

mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the sheep primary fibroblast preparation or sheep of Salamonsen to provide patentable distinction over the sheep cell preparation and sheep of the claims. Thus at the time of the present invention, the ordinary artisan would have found the claimed sheep cell preparation and sheep obvious over the sheep cell preparation and sheep disclosed by Salamonsen.

Claims 70, 72, 74, 79, and 81 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over D'Andrea et al (1994) J. Reproduct. Fertil. 102, pp. 185-194 (pig).

D'Andrea teaches a pig primary uterine fibroblast preparation (page 186, col. 2, parag. 4 to page 187, line 6.) In so teaching, D'Andrea inherently teaches a live-born pig. Thus, the primary fibroblasts and pig donor of D'Andrea cannot be distinguished from the pig cell preparation and pig of the claims. If the primary fibroblast preparation and donor pig of D'Andrea were compared side-by-side to the claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the pig. Thus, D'Andrea clearly anticipates the claimed invention.

In the alternative the pig primary uterine fibroblast preparation and pig taught by D'Andrea render obvious the claimed cell preparation and pig as there is no disclosed or discernable patentable distinction between D'Andrea's cell preparation and pig and those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the pig primary fibroblast preparation or pig of D'Andrea to provide patentable distinction over the pig cell preparation and pig of the claims. Thus at the time of the

present invention, the ordinary artisan would have found the claimed pig cell preparation and pig obvious over the pig cell preparation and pig disclosed by D'Andrea.

Claims 70, 72, 75, 79, and 82 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barker et al (1973) Proc. Natl. Acad. Sci. (USA) Vol. 70, pp 1739-1743 (goat).

Barker teaches a goat primary bone marrow preparation (page 1739, col. 2, parag. 1 and page 1741, col. 1, parag. 1). In so teaching, Barker inherently teaches a live-born goat. Thus, the goat primary bone marrow cells and goat donor of Barker cannot be distinguished from the goat cell preparation and goat of the claims. If the primary bone marrow preparation and donor goat of Barker were compared side-by-side to the claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the goat. Further, the goat of Barker was a live offspring at some point in time. Thus, Barker clearly anticipates the claimed invention.

In the alternative the goat primary bone marrow preparation and goat taught by Barker render obvious the claimed cell preparation and goat as there is no disclosed or discernable patentable distinction between Barker's cell preparation and goat and those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the goat primary bone marrow preparation or goat of Barker to provide patentable distinction over the goat cell preparation and goat of the claims. Thus at the time of the present invention, the ordinary artisan would have found the claimed goat cell preparation and goat obvious over the goat bone marrow cell preparation and goat disclosed by Barker.

Claims 70, 72, 76, 79, and 83 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yoshimura et al (1990) Proc. Natl. Acad. Sci (USA) 87, pp. 3670-3674. (mouse).

Yoshimura teaches a mouse primary marry epithelial cell preparation (page 879, col. 2, parag. 3, lines 1-5). In so teaching, Yoshimura inherently teaches a live-born mouse. Thus, the mouse primary marry epithelial cell preparations and mouse donor of Yoshimura cannot be distinguished from the mouse cell preparation and mouse of the claims. If the mouse primary marry epithelial cell preparation and donor mouse of Yoshimura were compared side-by-side to the claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the mouse. Further, the mouse of Yoshimura was a live offspring at some point in time. Thus, Yoshimura clearly anticipates the claimed invention.

In the alternative the mouse primary marry epithelial cell preparation and mouse taught by Yoshimura render obvious the claimed cell preparation and mouse as there is no disclosed or discernable patentable distinction between Yoshimura's mouse primary marry epithelial cell preparation and mouse and those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the mouse primary marry epithelial cell preparation or mouse of Yoshimura to provide patentable distinction over the mouse cell preparation and mouse of the claims. Thus at the time of the present invention, the ordinary artisan would have found the claimed mouse cell preparation and mouse obvious over the mouse primary marry epithelial cell preparation and mouse disclosed by Yoshimura.

Claims 70, 72, 77, 80, and 84 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adolphe et al. (1984) Exp. Cell Res. 155, pp. 527-536 (rabbit).

Adolphe teaches a rabbit primary chondrocyte preparation (page 528, parag. 2 and pages 529-530, bridg. parag). In so teaching, Adolphe inherently teaches a live-born rabbit. Thus, the rabbit primary chondrocyte preparation and rabbit donor of Adolphe cannot be distinguished from the rabbit cell preparation and rabbit of the claims. If the rabbit primary chondrocyte preparation and donor rabbit of Adolphe were compared side-by-side to the claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the rabbit. Further, the rabbit of Adolphe was a live offspring at some point in time. Thus, Adolphe clearly anticipates the claimed invention.

In the alternative the rabbit primary chondrocyte preparation and rabbit taught by Adolphe render obvious the claimed cell preparation and rabbit as there is no disclosed or discernable patentable distinction between Adolphe's rabbit primary chondrocyte preparation and rabbit and those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the rabbit primary chondrocyte preparation or rabbit of Adolphe to provide patentable distinction over the rabbit cell preparation and rabbit of the claims. Thus at the time of the present invention, the ordinary artisan would have found the claimed rabbit cell preparation and rabbit obvious over the rabbit primary chondrocyte preparation and rabbit disclosed by Adolphe.

Claims 70, 72, 78, 79, and 85 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stirling et al (1990) J. Biol. Chem. 265, pp. 5-8 (bovine).

Stirling teaches a bovine primary luteal cell preparation (page 6, col. 1, parag. 1, lines 1-18 and page 6, figs. 1 and 2). In so teaching, Stirling inherently teaches a live born bovine. Thus, the bovine primary luteal cell preparation and bovine donor of Stirling cannot be distinguished from the bovine cell preparation and bovine of the claims. If the bovine primary luteal cell preparation and donor bovine of Stirling were compared side-by-side to the claims, there would be no feature that distinguishes them from one another, nor could it be determined which was first, the cells or the bovine. Further, the bovine of Stirling was a live offspring at some point in time. Thus, Stirling clearly anticipates the claimed invention.

In the alternative the bovine primary luteal cell preparation and bovine taught by Stirling render obvious the claimed cell preparation and bovine as there is no disclosed or discernable patentable distinction between Stirling's bovine primary luteal cell preparation and bovine and those claimed. However, applicant has argued to earlier presented rejections that there would be genomic DNA nucleotide differences between the cited mammals and those claimed as clones. As rebuttal, there is no evidence that any of these purported differences materially alter the bovine primary luteal cell preparation or bovine of Stirling to provide patentable distinction over the bovine cell preparation and bovine of the claims. Thus at the time of the present invention, the ordinary artisan would have found the claimed bovine cell preparation and bovine obvious over the bovine primary luteal cell preparation and bovine disclosed by Stirling.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

Should inquiries be made on or after January 12, 2004, the examiner's phone number will be 571-272-0727. Deborah Reynolds will be reached at 571-272-0734.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

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